

REMARKS

Claims 1 through 26 are pending in this application.

Claims 1, 3, 5, 7, 15-18, 20, 22, 24 and 26 have been amended, and claim 25 has been canceled without disclaiming its subject matter.

No new matter has been added.

I. Claim Rejection – 35 U.S.C. §112

Claims 3-8, 11, 25 and 26 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention.

The examiner argued that it is unclear what is encompassed by the phrase, “an (AluSTY_a/AluSTX_a) locus.”

The examiner also argued that the terms the “AluSTY_a” and “AluSTX_a” are not equivalent to the generally accepted standardized nomenclature used for Alu repeats, reciting Batzer et al. “Standardized Nomenclature for Alu Repeats”, Journal of Molecular Evolution, 1996, 42: pages 3-6 (hereinafter “the Batzer reference”).

To avoid confusion, the article “an” before the term “locus” has been deleted.

The test for 35 U.S.C. 112 is not whether the terminology is a standardized nomenclature.

The first sentence of the second paragraph of 35 U.S.C. 112 requires only that claims “set out and circumscribe a particular area with *a reasonable degree* of precision and particularity.” *In re Miller*, 442 F.2d 689, 692 (CCPA 1971), *quoting In re Moore*, 439 F.2d 1232, 1235 (CCPA 1971) (emphasis added). The legal standard for definiteness is whether a claim reasonably

apprises those of skill in the art of its scope. (*Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), *cert. denied*, 112 S.Ct. 169 (1991)). So long as the scope of the subject matter encompassed by the claims is clear, and applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph no matter how broad the claim language. See *In re Miller*, 441 F.2d 689, 692-93, 169 USPQ 597, 599 (CCPA 1971); *In re Kamal*, 398 F.2d 867, 870, 158 USPQ 320, 322 (CCPA 1968).

Here, since the disclosure is not different from what is defined by the claims, the only issue is whether one of ordinary skill in the art would be apprised of the scope of the claim in view of the term “AluSTY_a” and “AluSTX_a”.

It should be noted that the author, Dr. Batzer, of the Batzer reference is one of the inventors of the present application. The Batzer reference stated that “[w]e have attempted to combine some of the preexisting nomenclature with newer names to provide a basis for naming Alu sequences” (see the left column, second paragraph on page 4), and that “this selection is not meant to be an exhaustive selection of all possible subfamilies, but simply a reasonable working nomenclature for those older subfamilies” (see the right column, first paragraph on page 4). That is, the Batzer reference did not show that the terms “(AluSTY_a/AluSTX_a) locus” are not equivalent to the generally accepted standardized nomenclature used for Alu repeats. Also, as stated above, the use of the standardized nomenclature is not necessary only if claims set out and circumscribe a particular area with *a reasonable degree* of precision and particularity. In this case the terms “(AluSTY_a/AluSTX_a) locus” are precise to the invention in that “AluSTY_a” is an Alu element for Sex Typing (“ST”) of the “Y” chromosome and “AluSTX_a” is for Sex Typing (“ST”) of the “X” chromosome.

The loci of *AluSTY*a and *AluSTX*a are known in the art, and conventionally used in the art to which the invention pertains.¹ Please also note that the present invention was also published in *Analytical Biochemistry* 312 (2003) 77-79. The fact that the journal accepted the use of the phrase “*AluSTY*a and *AluSTX*a loci” supports that the phrase is well known and conventionally used in the art to which the instant invention pertains. Therefore, one of ordinary skill in the art would be apprised of the scope of the claim in view of the phrase. “*AluSTY*a” and “*AluSTX*a.” That is, the ordinary skilled person in the art can know what sequence each locus is drawn to and where each locus is found in each respective chromosome.

II. Claim Rejections

Claims 1, 2, 10 and 12 are rejected under 35 U.S.C. §102(b) as being anticipated by Wilson et al. (“Sexing of Human and Other Primate DNA” *Biological Chemistry*. October 1998. Vol. 379” Pages 1287-1288.)

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. in view of Schumm et al. ‘660.

Claim 24 is rejected under 35 U.S.C. §103(a) as being unpatentable over Wilson et al. in view of Wang et al. (“Quantitation of mRNA by the polymerase chain reaction” *Proc. Natl. Acad. Sci.* December 1989. Vol. 86: Pages 9717-9721.)

Claim 1 has been amended to recite “amplifying at least one locus containing one of *AluSTY*a locus and *AluSTX*a locus of the DNA sample in an amplification reaction.” Claim 24 has been amended to recite “amplifying at least one locus of *AluSTY*a and *AluSTX*a in the sample by a polymerase chain reaction.”


¹ You may see one of the examples using the phrase, the “*AluSTY*a and *AluSTX*a loci” at the website of http://etd.lsu.edu/docs/available/etd-03232005-161807/unrestricted/Hedges_Dissertation.pdf.

Since the examiner stated that no prior art teaches or suggest the amplification of the AluSTXa or AluSTYa locus for use in a gender determination assay, claims 1 and 24 and their dependent claims 2-12 and 26 are allowable.

No fee is incurred by this Amendment.

In view of the above, all claims are deemed to be allowable and this application is believed to be in condition to be passed to issue. Reconsideration of the rejections and objections is requested. Should any questions remain unresolved, the Examiner is requested to telephone Applicant's attorney.

Respectfully submitted,


Robert E. Bushnely
Attorney for the Applicant
Registration No.: 27,774

1522 "K" Street N.W., Suite 300
Washington, D.C. 20005
Tel. No. (202) 408-9040
Facsimile No. (202) 289-7100

Folio: P56884
Date: 12/12/2005
I.D.: REB/JHP